January 20, 2004

Division of Dockets Management (HFA-305)
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

Re: Two Guidance on Qualified Health Claims
FDA Docket No. 2003N-0069
68 Fed. Reg. 41387 (July 11, 2003)

On December 18, 2002, FDA announced a major new initiative, the Consumer Health Information for Better Nutrition Initiative. This initiative is part of the agency's continuing implementation of the Court of Appeals decision in Pearson v. Shalala and the District Court decisions that followed.[1] A Task Force was established by the Commissioner of Food and Drugs and charged with preparing a report on the implementation of this initiative. The Task Force established FDA Docket No. 2003N-0069 to receive views and comments from interested persons.

Because the issues raised by the new initiative cut across the entire food industry, several food trade associations formed a Coalition, chaired by the Grocery Manufacturers of America, to provide consolidated comments to FDA on this matter. Attached is a copy of the comments submitted to that Docket on May 14, 2003.

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[1] Pearson v. Shalala, 164 F.3d 650 (D.C. Cir. 1999), rehearing denied, 172 F.3d 72 (D.C. Cir 1999) (en banc.), 130 F. Supp. 2d 105 (D.D.C. 2001), 141 F. Supp. 2d 105 (D.D.C. 2001); Whittaker v. Thompson, 248 F. Supp. 2d 1 (D.D.C. 2002).

For the same reasons that the Coalition submitted its comments in May with respect to the new initiative, the same Coalition, with additional trade associations that have joined in the interim, now submits these comments with respect to the two final interim guidance documents that are the subject of the FDA notice in 68 Fed. Reg. 41387 (July 11, 2003): (1) the Interim Evidence-Based Ranking System for Scientific Data and (2) the Interim Procedures for Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements.

Executive Summary

Interim Evidence-Based Ranking System for Scientific Data

The interim guidance should be clarified to emphasize that the focus of any rating system must be on the evidence in support of the specific claim involved, not just the nutrient-disease relationship. The precise wording of the claim will determine what specific data are relevant for rating. Because rating scientific evidence is necessarily a subjective, not an objective, process, FDA must be very flexible in recognizing creative claims that adequately reflect the continuum of scientific evidence rather than the four arbitrary categories posited by FDA.

The interim guidance should be revised to recognize that scientific information other than human clinical data may well be important in supporting health claims for food products. A credible dispute resolution mechanism should be included to resolve any scientific issues that arise.

Interim Procedures for Qualified Health Claims

The Coalition strongly supports the pre-market notification procedure adopted in the interim guidance. Both the filing of a pre-market notification and the final FDA determination on the matter should be the subject of a Federal Register notice. The qualifying language suggested in the interim guidance cannot be applied rigidly by FDA, but could be regarded as a "safe harbor" without the need for further testing or discussion.

Interim Evidence-Based Ranking System for Scientific Data

This interim guidance would designate four categories of scientific data (A through D) and establish a six-part evidence-based rating system that would result in ranking the totality of the evidence in accordance with the four categories of scientific data described above.

1. The Coalition agrees with FDA that the weight of the scientific evidence in support of a claim about the relationship between a nutrient and disease will determine the relative strength with which the claim may be worded in order to assure that it is truthful and not misleading. The Coalition urges that the interim guidance be clarified to emphasize that the focus of any rating system must be on the weight of the evidence in support of the specific claim involved. Although this will inherently involve consideration of the disease relationship, Section 403(r)(1)(B) of the Federal Food, Drug, and Cosmetic Act makes it clear that the primary issue to be addressed is the relationship of the scientific evidence to the proposed claim in the label or the labeling of a food. Accordingly, the precise wording of the claim will determine what scientific data are relevant for rating.

2. The Coalition also wishes to emphasize that the rating of the weight of any body of scientific evidence is necessarily a subjective, not an objective, process. The weight of scientific evidence exists in a continuum, not in a series of well-defined categories. Put simply, the weight of the scientific evidence in support of a claim cannot always be fit into a neat classification such as the four categories (A through D) posited by FDA. The boundaries between these four categories are not clear-cut. Reasonable scientists will undoubtedly reach different conclusions in rating the identical body of scientific evidence.

Accordingly, if FDA pursues this approach, the agency must be very flexible and recognize that these four categories represent arbitrary and rigid distinctions that will in many instances not be susceptible to objective analysis. The weight of scientific evidence will often reside at the boundaries between these four categories, requiring flexibility in the application of the FDA rating system. Creativity in formulating appropriate claims that adequately reflect the continuum of scientific evidence -- rather than the four arbitrary categories posited by FDA -- is therefore essential to the success of this approach.

3. The Coalition notes that, as presently worded, the interim rating and ranking system would rely only upon human clinical data. The Coalition believes that other scientific evidence may well be important in supporting health claims for food products. Such evidence would include in vitro data, the results of animal experimentation, and scientific evidence on the mechanism of action involved in any nutrient/disease relationship. The Coalition therefore urges FDA to include in the final guidance reference to scientific information other than clinical data.

4. Because the interim rating and ranking system set forth by FDA in the interim guidance is inherently and irretrievably subjective, it is important that FDA establish a credible dispute resolution mechanism to resolve scientific issues that will inevitably arise in the application of this interim guidance. The Coalition endorses, as a model, the dispute resolution approach in the draft guidance on a process for resolving disputes arising over scientific and technical issues related to pharmaceutical current good manufacturing practices (cGMP) announced by FDA on September 3, 2003. A tier one dispute resolution should be handled at the

Center level, and a tier two dispute resolution should be handled through a neutral panel of scientific experts at the level of the Office of the Commissioner.

Interim Procedures for Qualified Health Claims

As a general matter, the Coalition strongly supports the pre-market notification procedure adopted by FDA for qualified health claims in this interim guidance. The interim procedure closely follows the approach recommended by the Coalition in its May 14, 2003 comments, a copy of which is attached. For the reasons set forth in those attached comments, the Coalition urges FDA to retain this approach, with the modifications suggested below.

1. The Coalition continues to believe that the filing of a qualified health claim premarket notification should be the subject of a Federal Register notice, providing time for public comment, and that the final FDA determination with respect to a premarket notification should be the subject of a brief notice that is also published in the Federal Register. Additional information would, of course, also be appropriate for posting on the FDA website. The Coalition strongly supports a transparent process and believes that Federal Register publication of the two seminal events -- the filing of the premarket notification and the ultimate FDA decision on the matter -- will assure the most widespread public notice.

2. The Coalition has pointed out above that the weight of scientific evidence in support of a particular claim will not always fit neatly into the four-category scheme posited by FDA. Accordingly, the qualifying language suggested in this interim guidance as appropriate for a particular category cannot be applied rigidly by FDA, for several important reasons. First, the First Amendment to the Untied States Constitution requires that FDA permit the use of any

explanatory or qualifying terms that accurately convey the weight of the scientific evidence and are not misleading. Second, where the weight of the scientific evidence falls midway between any two of the FDA categories, it will be necessary to fashion appropriate qualifying language that reflects the weight of the scientific evidence rather than just using the standard phrases set forth by FDA in the interim guidance. In short, the focus must always be on the accuracy, truthfulness, and nonmisleading nature of whatever claim is presented in a premarket notification, and not upon the use of some standardized terminology offered by FDA.

At most, the standardized qualifying language suggested by FDA in the interim guidance might serve as a "safe harbor" that could, in the discretion of the person submitting the premarket notification, be adopted without the need for further discussion. Where a premarket notification submits different terminology, however, FDA must consider it in the light of First Amendment principles and cannot deny it absent empirical evidence that it is false or misleading. This is particularly true where the premarket notification contains consumer survey evidence demonstrating that the proposed claim meets the new FDA "reasonable person" standard. In this respect, the work of the International Tree Nut Council in supporting its proposed claim by submission of consumer survey evidence can serve as a model.

Conclusion

In summary, the Coalition commends FDA, and in particular the Task Force, for the important work that it has done in these two interim guidances that further implement the Pearson and Whittaker court decisions. With the minor modifications recommended in these comments, these guidances will provide a strong foundation for the new Consumer Health

Information for Better Nutrition Initiative and will allow the food industry to make available more and better information about the food supply to help American consumers improve their health and prevent disease by making sound dietary decisions.

Grocery Manufacturers of America, Chair
American Bakers Association
American Frozen Food Institute
Association for Dressings and Sauces
Calorie Control Council
Institute of Shortening and Edible Oils
International Dairy Foods Association
International Food Additives Council
International Tree Nut Council
Juice Products Association
National Association of Margarine Manufacturers
Snack Foods Association
Vinegar Institute

May 14, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket No. 02D-0515
Guidance for Industry: Qualified Health Claims in the Labeling of Conventional Foods and Dietary Supplements

Enclosed is a document entitled "Proposed FDA Regulation to Establish a Premarket Notification Program for Qualified Health Claims for Food Labeling," together with an attached draft regulation. The document and the attachment constitute the comments of the following associations in connection with Docket No. 02D-0515: The Grocery Manufacturers of America, The Snack Foods Association, The Institute of Shortening & Edible Oils, Inc., and The National Restaurant Association.

Sincerely yours,

James H. Skiles
Vice President, General Counsel
Grocery Manufacturers of America

Proposed FDA Regulation to Establish a Premarket Notification Program for Qualified Health Claims for Food Labeling

Introduction

This analysis accompanies the attached draft regulation that would establish a premarket notification, rather than a premarket approval, program under which FDA would review proposed qualified health claims for food labeling. It would apply to health claims that do not meet the statutory standard of "significant scientific agreement" established in section 403(r)(3)(B)(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) but that do meet the lower standard of credible scientific evidence established in the Pearson litigation.[1]

Definition of a "Qualified Health Claim"

In the Pearson case, the United States Court of Appeals for the District of Columbia Circuit characterized the type of scientific information sufficient to support a health claim under the First Amendment to the United States Constitution as "credible evidence."[2] The court placed the burden on FDA to demonstrate with "empirical evidence" that a qualified claim is nonetheless deceptive and can therefore can be banned.[3] The United States District Court, in the litigation that followed the decision of the Court of Appeals, has adopted a "credible scientific evidence" standard.[4]

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[1] Pearson v. Shalala, 164 F.3d 650 (D.C. Cir. 1999), rehearing denied, 172 F.3d 72 (D.C. Cir. 1999) (en banc), 130 F. Supp. 2d 105 (D.D.C. 2001), 141 F. Supp. 2d 105 (D.D.C. 2001); Whitaker v. Thompson, D.D.C. Civ. No. 01-1539 (GK) (December 24, 2002).

[2] 164 F.3d at 658.

[3] Id. at 659.

[4] See particularly the most recent District Court opinion, in Whitaker v. Thompson, supra note 1.

Accordingly, the draft regulation provides that a qualified health claim must be supported by information that constitutes credible scientific evidence but that does not reach the statutory standard of significant scientific agreement that would justify an unqualified health claim. The definition acknowledges that a qualified health claim must either be worded, or qualified by explanatory information, disclaimers, or other qualification, to assure that the claim accurately conveys the supporting information and is not misleading. In many instances, the wording of a claim itself will incorporate a limitation or qualification, or will be accompanied by explanatory information, thus making frank disclaimers unnecessary. It is preferable to include the limitations and qualifications as a direct and integral part of the claim, rather than using disclaimers that conflict with the claim, because a claim that first states the matter positively and then qualifies it negatively will be far less understandable and useful to consumers.

The draft regulation includes a definition of "credible scientific evidence." The standard of credible scientific evidence would be met by any scientific study that satisfies long-established principles of scientific investigation -- e.g., a written protocol that describes the investigation in adequate detail, the informed consent of the test subjects, a statistical analysis of the results, and a written report reviewing the investigation and containing the conclusion. The type and quantity of evidence required to support a claim will depend on how the claim is worded, i.e., on exactly what claim is being made.

In determining whether a claim is misleading, the draft regulation adopts the "reasonable person" standard announced by FDA in its most recent guidance, released on December 18, 2002.[5] It is unnecessary to state in this definition that a qualified health claim

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[5] 67 Fed. Reg. 78002 (December 20, 2002).

supported by credible scientific evidence must be permitted by FDA, under the First Amendment, unless the agency can demonstrate by empirical evidence that it is misleading or deceptive. The courts have already established this legal principle and it is unnecessary to repeat it in the definition.

The courts have held, in earlier litigation, that the requirement in the FD&C Act for submission of a proposed health claim to FDA, and an FDA decision on that proposed claim, prior to use of the claim, does not violate the First Amendment.[6] Accordingly, whether a proposed health claim is a significant scientific agreement claim or a credible scientific evidence claim, it is subject to review by FDA prior to use in the marketplace.

Relationship of a Qualified Health Claim to a Significant Scientific Agreement Claim

Section 101.70 of the current FDA regulations contains the requirements for petitions for significant scientific agreement claims. Until now, all qualified health claims have been initiated through a petition under Section 101.70 for a significant scientific agreement claim. After FDA has determined that the petition does not meet the significant scientific agreement standard, the agency has then engaged in discussion with the petitioner and ultimately permitted a qualified health claim by a letter that is then posted on the FDA website. Accordingly, it is appropriate to amend Section 101.70 specifically to recognize this process. The draft regulation would add a new subsection (k) to Section 101.70 to state that, if a significant scientific agreement petition is denied, two alternative procedures may be followed. First, the petition may be converted to a premarket notification for a qualified health claim without the submission of any additional documents. Second, the person who submitted the

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[6] Nutritional Health Alliance v. Shalala, 144 F.3d 220 (2d Cir. 1998).

petition may withdraw it and then submit a premarket notification. The draft regulation emphasizes that submission of a significant scientific agreement claim petition is not a prerequisite to submission of a qualified health claim premarket notification.

Procedure for Premarket Notifications for Qualified Health Claims

In order to establish a premarket notification procedure for qualified health claims, a new Subpart would be added to the existing Part 101 of the FDA regulations, which governs food labeling. New Section 101.20 would set forth the entire new procedure for qualified health claims.

There are sound public policy reasons, as well as legal authority, for establishing a separate premarket notification process for qualified health claims independent of the pre-market approval requirements for significant scientific agreement claims.

First, this is essentially the same procedure that FDA has in fact been following under the Pearson decision. Petitions for significant scientific agreement claims have been converted to the equivalent of qualified health claims notifications, and FDA has made its determinations through letters rather than through notice-and-comment rulemaking. This process is entirely lawful and need not be changed.

Second, it would be burdensome and wasteful for both FDA and the regulated industry to require that a claim that the interested person knows does not meet the significant scientific agreement standard nonetheless be the subject of a full petition for such a claim, only to be turned down and then reconsidered as a qualified health claim. Instead, interested persons should be encouraged to submit a request directly for a qualified health claim where there is credible scientific evidence but not significant scientific agreement.

Third, a premarket notification procedure is more efficient and requires fewer resources at FDA. Under the FD&C Act, a significant scientific agreement claim must be the

subject of full notice-and-comment rulemaking, thus requiring the development of two extensive preambles analyzing all the scientific evidence. Because a qualified health claim is a constitutional right for which there is no mandatory procedure under the FD&C Act, on the other hand, it is not subject to the statutory requirement of notice-and-comment rulemaking and can be the subject of any reasonable and efficient administrative process. Recent FDA experience in analogous situations has demonstrated that premarket notification is much more efficient, and no less effective, than a premarket approval system. FDA has replaced premarket approval with premarket notification for review of GRAS substances[7] and food contact materials[8] and has established a premarket notification procedure for reviewing food derived from genetically modified plants as well.[9]

Fourth, it can be anticipated that a significant scientific agreement claim will be less likely to be the subject of new scientific evidence that requires a change in the claim than a qualified health claim. By definition, a qualified health claim arises at an earlier stage of scientific development. Such a claim may well be required to be changed as new scientific information emerges. Accordingly, a more flexible procedure, that allows FDA or interested persons to initiate a change in a qualified health claim, is justified.

Fifth, the use of premarket notification rather than premarket approval does not require or imply that the submission made to FDA will contain any less information, or that FDA will provide any less intensive review of that information. The draft regulation makes it clear that the same categories of information will be required to be included in a premarket

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[7] 62 Fed. Reg. 18938 (April 17, 1997).

[8] 67 Fed. Reg. 35724 (May 21, 2002).

[9] 57 Fed. Reg. 22984 (May 29, 1992).

notification as in a premarket approval petition. FDA will be expected to review both with the same degree of scrutiny. The only difference is that FDA is not required to write two lengthy and detailed preambles, but instead will conclude its review of a qualified health petition in the same way that it does now, by specifying the permitted qualified health claim and stating that the agency has no objection to the claim.

Subsection (a) of the draft regulation simply provides that any interested person could submit a premarket notification for a qualified health claim. The proposed claim could be for a specific food (including a category or group or type of foods) or a food component or ingredient. The remainder of the requirements in this subsection would follow those in Section 101.70(a) for significant scientific agreement petitions.

Subsections (b)-(i) of the draft regulation would contain the same requirements for a premarket notification for a qualified health claim that currently exist for a petition for a significant scientific agreement claim. Only minor wording changes have been made. Sentences have been added to make it clear that the scientific evidence relied upon as support for a qualified health claim may or may not be published and may or may not be peer reviewed and that consumer testing may be submitted as part of the supporting information. The draft regulation also incorporates the credible scientific evidence standard already discussed above.

Subsection (j) of the draft regulation would establish the premarket notification procedure. It provides that, within 30 days of receipt of the notification, FDA would inform the person submitting the notification of the date on which the notification was received and, if it is filed by FDA, would publish a notice of filing in the Federal Register. If the notification is not filed by FDA, because it is deficient in some respect, FDA would inform the person submitting the notification of all the deficiencies and the notification could be resubmitted at a later date.

All of the contents of the notification would become public upon the publication of the notice of filing. Thus it would be an open and transparent process.

Within 60 days after the publication of a notice of filing, any other interested person could submit any data, information, or comment pertinent to the notification. FDA would then take into account all of the additional submitted information as part of its consideration of the notification. Interested persons could, for example, submit additional pertinent information and could suggest additional proposed claims, or an expansion or contraction of the proposed claims submitted as part of the notification. Interested persons could also suggest additional categories of food or dietary supplements to which the claim would appropriately apply. There would be no limitation on the type of comment that could be submitted during this 60-day period. This would be designed to encourage all persons interested in a particular type of claim to join in one proceeding, thereby substantially consolidating and reducing the FDA workload. In order to assure a fair process, however, no comment submitted after the 60-day period would be considered by FDA in making its determination with respect to the notification. Such information could, of course, be considered by FDA at a later date.

Within 180 days of the date of the notice of filing of the notification, FDA would inform the person who submitted the notification that the agency objects to the proposed qualified health claim, or that it does not object to the proposed claim, or that it objects to the specific claim or claims set forth in the notification but does not object to a revised claim or claims. No claim could be used until FDA informs the person who submitted the notification that the agency has no objection to the claim. Thus, no qualified health claim could be used, under any circumstances, prior to FDA review and a decision by the agency that it has no

objection. A person who wishes to use a revised claim must submit a new premarket notification.

If FDA objects to the proposed qualified health claim, the person who submitted the notification would have the legal right to challenge that FDA decision in court under the First Amendment standards established in the Pearson litigation. There is no need, however, to spell out this legal right in the draft regulation. When FDA objects to a claim, the agency would be required to spell out its reasons in writing and to explain why no qualification of the claim would make the claim not misleading to a reasonable person.

If FDA does not object to an alternative form of a claim that the person submitting the notification nonetheless finds unacceptable, the person also has the right to challenge the FDA decision in the courts. In the meanwhile, FDA could publish the claim in spite of a court challenge, and anyone could use the claim who wishes to do so.

In some instances, FDA may find that 180 days is insufficient time in which to make a decision on a proposed qualified health claim. The draft regulation would provide for the possibility of two extensions of 30 days each.

All of the qualified health claims that have been agreed to by FDA thus far have been the result of informal discussion between the person who submitted the claim and the responsible FDA officials. This is a far more efficient and effective process than relying on the repeated exchange of formal documents. Accordingly, the draft regulation would emphasize that the parties shall engage in informal discussions throughout the review period in order to attempt to reach agreement on an appropriate qualified health claim.

An FDA decision that it has no objection to a qualified health claim has thus far been made in the form of a written letter stating its decision and the specific qualified health

claim involved. This letter has been placed on the FDA internet website. The draft regulation would propose to retain this procedure. The draft regulation would also require FDA simply to publish a brief notice of the new qualified health claim in the Federal Register, in order to provide adequate notice to the entire public.

Finally, new information may arise that requires consideration of a change in a qualified health claim. The person who submitted the notification could at any time submit to FDA a new notification proposing such a change, using the same form already described for a premarket notification. FDA could also, at any time, inform the person who submitted the original premarket notification that based on new information the agency believes that a claim should be reworded or withdrawn. After full and frank discussion between the parties, if FDA concludes that its earlier letter should be modified or withdrawn, it would have the right to do so. Thereafter no person could use the qualified health claim except in compliance with the new FDA letter. The person who agreed to the earlier qualified health claim could, of course, contest such FDA action in the courts.

Proposed FDA Regulations
To Establish
A Premarket Notification Program
For
Qualified Health Claims For Food Labeling

1. Amendment of 21 C.F.R. 101.14: General Requirements for Health Claims

Section 101.14(a) would be amended to add the following new definition at the end thereof:

(6) Qualified health claim means a health claim (i) for which the supporting information constitutes credible scientific evidence but is not sufficient to justify a determination of significant scientific agreement among experts qualified by training and experience to evaluate such claims and (ii) which is worded or is qualified by explanatory information, disclaimers, or other qualifications in a way that accurately conveys the supporting information and is not misleading to a reasonable person. For purposes of this section and § 101.120 of this part, credible scientific evidence shall mean evidence obtained in accordance with established principles of scientific investigation. A qualified health claim is subject to the premarket notification requirements in subpart H of this part.

2. Amendment of 21 C.F.R. 101.70: Petitions for Health Claims

Section 101.70 would be amended to add the following new paragraph at the end thereof:

(k) Qualified health claim. If a petition is denied or deemed denied either before or after a comprehensive review, the petition may, with the consent of the petitioner, be converted to a premarket notification for a qualified health claim under subpart H of this part or the petitioner may withdraw the petition and submit a premarket notification for a qualified health claim under subpart H of this part. Submission of a petition under subsection (a) of this section is not required prior to submission of a notification under § 101.120(a) of this part for a qualified health claim.

3. Amendment of 21 C.F.R. Part 101: Food Labeling

Part 101 would be amended by adding the following new subpart at the end thereof:

Subpart H -- Qualified Health Claims

§ 101.120 Premarket notifications for qualified health claims.

(a) Premarket notifications. Any interested person may submit a premarket notification to the Food and Drug Administration (FDA) for a qualified health claim for use in the labeling of a food (including a category or group or type of foods) or food component or ingredient. An original and one copy of the notification shall be submitted, or the person submitting the notification may submit an original and a computer readable disk containing the notification. If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation. The notification shall state the post office address to which any correspondence may be sent.

(b) Incorporation by reference. Pertinent information may be incorporated in, and will be considered as part of, a notification on the basis of specific reference to such information submitted to and retained in the files of FDA. Such information may include any findings, along with the basis of the findings, of an outside panel with expertise in the subject area. Any reference to published information shall be accompanied by reprints or easily readable copies of such information.

(c) Nonclinical studies. If nonclinical laboratory studies are included in a notification, the notification shall include, with respect to each nonclinical study, either a statement that the study has been conducted in compliance with the good laboratory practice

regulations set forth in part 58 of this chapter or a brief statement of the reasons for noncompliance.

(d) Clinical investigations. If clinical or other human investigations are included in a notification, the notification shall include a statement that they were either conducted in compliance with the requirements for institutional review set forth in part 56 of this chapter or not subject to such requirements in accordance with § 56.104 or § 56.105 of this chapter, and a statement that they were conducted in compliance with the requirements for informed consent set forth in part 50 of this chapter or a brief statement of the reasons for noncompliance.

(e) Public disclosure. All information in a notification is available for public disclosure after FDA publishes in the Federal Register a notice that the notification has been filed. Clinical investigation reports, adverse reaction reports, product experience reports, consumer complaints, and other similar information shall only be available after deletion of:

(1) Names and any information that would identify the person using the product.

(2) Names and any information that would identify any third party involved with the report, such as a physician or hospital or other institution.

(f) Form for notifications. A notification for a qualified health claim shall include the following information and be submitted in the following form:

(Date)_____

Name of person submitting the notification_____

Post office address_____

Subject of the notification_____

Office of Nutritional Products, Labeling, and Dietary Supplements (HFS-800)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

The undersigned, _____, submits this premarket notification pursuant to section 101.120 of the FDA regulations with respect to (statement of the food or food component or ingredient and its qualified health claim). Attached hereto, and constituting a part of this notification, are the following:

A. Preliminary requirements. A complete explanation of how the food or food component or ingredient conforms to the requirements of § 101.14(b) of this part. For notifications where the subject is a substance that is added to food as an ingredient, the person submitting the notification should compile a comprehensive list of the specific ingredients that will be added to the food for purposes of the qualified health claim. For each such ingredient listed, the person submitting the notification should state how the ingredient complies with the requirements of § 101.14(b)(3)(ii) of this part, e.g., that its use is generally recognized as safe (GRAS), listed as a food additive, or authorized by a prior sanction issued by FDA, and the basis for the GRAS, food additive, or prior sanction status.

B. Summary of scientific information. The summary of scientific information provides the basis for a qualified health claim.

1. The summary shall establish that there is credible scientific evidence to support the claim and that the way that the claim is worded (including any explanatory information, disclaimers, or other qualifications) accurately conveys the supporting information and is not misleading. The supporting information may be published or unpublished and, if

published, may or may not be in a peer reviewed publication. In determining whether a claim is not misleading, the standard used by FDA is whether the claim is understood by a reasonable person. The supporting information may include the results of consumer testing of a proposed claim.

2. The summary shall be organized to support the specific wording of the claim that is the subject of the notification, including any explanatory information, disclaimer, or other qualifications to assure that the claim is accurate and not misleading. The summary shall state what actual or potential useful information may be provided to the public by the claim. If the claim is intended for a specific group within the population, the summary shall specifically address how the information in the claim may be useful to that population. Issues addressed in the summary shall include answers to such questions as (i) whether there is an optimum level of the particular food or food component or ingredient to be consumed, (ii) whether there is any level at which an adverse effect from the food or food component or ingredient occurs for any segment of the population, (iii) whether there are certain populations that must receive special consideration, and (iv) whether there are other nutritional or health factors (both positive and negative) that are important to consider when consuming the food or food component or ingredient.

3. The summary shall include a detailed analysis of the potential effect of the use of the claim on food consumption, and specifically any change due to significant alterations in eating habits and corresponding changes in nutrient intake resulting from such changes in food consumption. The latter analysis shall specifically address the effect on the intake of nutrients that have beneficial and negative consequences in the total diet.

4. If the claim is intended for a significant subpopulation within the general United States population, the summary shall specifically address the dietary practices of such group and shall include data sufficient to demonstrate that the dietary analysis is representative of such group (e.g., adolescents or the elderly).

5. If appropriate, the summary shall explain the prevalence of the disease or health-related condition in the United States population and the relevance of the claim in the context of the total daily diet.

C. Analytical methods and data. If the claim is for a food component or ingredient, analytical data that show the amount of the component or ingredient that is present in representative foods that would be candidates to bear the qualified health claim should be obtained from representative samples using methods from the Association of Official Analytical Chemists (AOAC) where available. If no AOAC method is available, the person submitting the notification shall submit the assay method used and data establishing the validity of the method for assaying the component or ingredient in food. The validation data should include a statistical analysis of the analytical and product variability.

D. Qualified health claim. One or more proposed qualified health claims that represent statements that may be used in food labeling to characterize the relationship between the food or food component or ingredient to a disease or health-related condition that is justified by the summary of scientific data provided in section C of the notification. The wording of the claim, taken as a whole (including any explanatory information, disclaimers, or other qualifications), shall be accurate and not misleading.

E. Attachments. The notification shall include the following attachments:

1. Copies of any computer literature searches done by the person submitting the notification (e.g., Medline).

2. Copies of articles cited in the literature searches and other information as follows:

a. All information relied upon for support of the claim, including copies of publications or other information cited in review articles and used to perform meta-analyses.

b. All information concerning adverse consequences to any segment of the population (e.g., sensitivity to the food or food component or ingredient).

c. All information pertaining to the United States population.

F. Environmental considerations. The person submitting the notification is required to submit either a claim for categorical exclusion under § 25.30 or § 25.32 of this chapter or an environmental assessment under § 25.40 of this chapter.

Yours very truly,

Person submitting the notification_____
By_____
(Indicate authority)

(g) Submission of information. The information specified under the several lettered headings should be submitted on separate pages or sets of pages, suitably identified. If such information has already been submitted with an earlier petition or notification from the person submitting the notification or in any other public petition or notification, the present notification may incorporate it by specific reference to the earlier petition or notification.

(h) Balanced information. The notification shall include a statement signed by the person responsible for the notification that, to the best of the knowledge of the person submitting the notification, it is a representative and balanced submission that includes unfavorable information as well as favorable information, known to the person submitting the notification to be pertinent to the evaluation of the qualified health claim.

(i) Signature. The notification shall be signed by the person submitting the notification or by an attorney or agent or (if a corporation) by an authorized official.

(j) Agency action.

(1) Within thirty days of receipt of the notification, FDA will inform the person submitting the notification of the date on which the notification was received and, if it is filed, shall publish a notice of filing in the Federal Register. If FDA does not file the notification, the agency shall inform the person submitting the notification of all deficiencies and the person may resubmit a revised notification at any time. All of the contents of the notification are available for public disclosure upon the publication of the notice of filing except for information that could identify persons using the product or any third party.

(2) Within sixty days after the publication of the notice of filing of the notification, any interested person may submit to the docket any information or comment pertinent to the notification.

(3) Within one hundred eighty days after the publication of the notice of filing of the notification, FDA will inform the person submitting the notification in writing either (i) that FDA objects to the proposed qualified health claim or (ii) that FDA does not object to the

proposed claim or (iii) that FDA objects to the proposed claim but does not object to a revised claim. Until FDA informs the person submitting the notification in writing that the agency does not object to a claim, no person may use the claim in food labeling.

(4) If FDA objects to a claim, the claim may not be used until such time as the person submitting the notification satisfies the FDA objection and receives a letter stating that FDA does not object to the claim. If FDA objects to a claim, the agency shall inform the person submitting the notification in writing of the reasons therefore, including justification of the rejection of any report from an authoritative scientific body. Any objection shall include the basis of the FDA determination that the proposed claim (or any variation discussed between FDA and the person submitting the notification) fails to convey the supporting information and is therefore misleading to a reasonable person. FDA shall object to a claim proposed in the notification or during the review process if the agency determines that no qualification of the claim will make the claim not misleading to a reasonable person.

(5) If FDA does not object to a claim, the person submitting the notification, and any other person, may begin using the claim in food labeling. Any deviation from the claim will require a separate notification under this section.

(6) If FDA objects to a proposed claim but does not object to a revised claim, the person submitting the notification may accept or reject the revised claim.

(7) For cause, FDA may extend, no more than twice, the period in which it will review the notification. Each such extension will be for no more than thirty days. FDA will inform the person submitting the notification of the basis for the extension, the length of the extension, and the date by which FDA will complete its review.

(8) FDA shall engage in informal discussion with the person submitting the notification throughout the review period in order to attempt to reach agreement with the person submitting the notification on the appropriate requirements for and wording of one or more claims to which the agency does not object.

(9) After FDA determines that it does not object to a claim, including a claim that the person submitting the notification has rejected, it shall send to the person submitting the notification a final letter stating its decision, place the letter on its internet web site, and publish in the Federal Register a brief notice of the new qualified health claim.

(10) FDA shall maintain on its internet web site both a complete copy of each final letter stating that the agency does not object to the claim set forth in the letter and a separate list of all of the claims to which it does not object.

(11) The person who submitted the notification may at any time submit a new notification proposing to modify a claim to which FDA has previously determined that it does not object. FDA may at any time, based upon new information (e.g., new scientific information that further supports or does not support the claim or empirical evidence that the claim is misleading to a reasonable person) received after the agency has stated that it does not object to a claim, inform the person who submitted the notification in writing that the agency believes that a claim should be reworded or withdrawn. The parties shall meet to attempt to reach agreement on the matter. If FDA concludes that its earlier letter should be modified or withdrawn, the agency shall inform the person who submitted the notification and shall post its new letter along with the earlier letter on its internet web site. Thereafter no person may use the claim except in compliance with the new letter.